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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,363	05/07/2001	Michael Franciscus W. C. Martens	294-100	2538

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/06/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/850,363	Applicant(s) MARTENS ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 14-18* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

The Amendment filed September 4, 2002 is acknowledged and has been entered.

Examiner's Remarks

It is noted that in the amendment filed on September 4, 2002 that the Applicant states (Remarks section) that claims 5-8 and 14 have been cancelled. However, there was no direct indication to specifically cancel claims 5-8 and 14 therefore, the claims are still pending. It is recommended to specifically state that claims 5-8 and 14 be cancelled.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4 the recitation "solidified" is vague. It is unclear if applicant intends that the antibody is immobilized to the reservoir or if the antibody is in a solid state?

Claim 1, line 5 "capable of" is vague and indefinite. The term is not a positive recitation. Does the reservoir contain a sample, a wash solution, and labeled monoclonal anti-insulin or anti-c peptide antibodies or not?

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanome et al (Immunoreactive proinsulin detected by enzyme-linked immunosorbent assay, Biomedical Research 18 (5) 389-393, 1997) in view of Landa et al (US 4,626,684).

Nakanome et al disclose a spectroscopic measurement device comprised of a microtiter plate and a microplate reader (page 390, column 2). Nakanome et al disclose that this microtiter plate contains wells (reservoirs) (page 389, column 2). Nakanome et al disclose that the well comprises monoclonal anti-C peptide antibodies and labeled anti-insulin antibody (see abstract). Nakanome et al disclose the addition of a washing solution to the well (page 389, column 2).

Nakanome et al differ from the instant invention in failing to specifically teach a photomultiplier detector.

Landa et al disclose a photomultiplier detector for fluorescence immunoassay (abstract and column 6). Landa et al disclose that the use of this photmultiplier detector provides for rapid and sensitive analysis and is practical in the clinical environment (col 2, lines 40-68).

It would have been obvious to one of ordinary skill in the art to substitute the photomultiplier detector such as taught by Landa et al for the microplate reader of Nakanome et al because Landa et al shows that the use of this photmultiplier detector provides for rapid and sensitive analysis and is practical in the clinical environment.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanome et al and Landa et al in view of Milford et al (US Patent 4,517,289).

See above for teachings of Nakanome et al and Landa et al.

Nakanome et al and Landa et al differ from the instant invention in failing to teach the labeled monoclonal anti-insulin antibody present in dried form.

Milford et al disclose the use of lyophilized monoclonal antibodies along with any other necessary reagents (col 8, lines 65-68). This allows for the antibody to be in stable form (col 8, line 67) and also is useful for the tissue typing of human tissues (col 3, lines 1-3).

It would have been obvious to one of ordinary skill in the art to incorporate the use of lyophilized antibodies as taught by Milford et al into the modified device of Nakanome et al because Milford et al shows that lypholization of antibodies allows the antibody to be in stable form and also is useful for the tissue typing of human tissues. Further, it is well known in the art to lyophilize antibodies for preservation and storage purposes.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanome et al and Landa et al in view of Campbell et al (US 4,946,958).

See above for teachings of Nakanome et al and Landa et al.

Nakanome et al and Landa et al differ from the instant invention in failing to teach the label is a chemiluminescent label.

Campbell et al disclose a chemiluminescent label which is conveniently linked to a monoclonal antibody or other protein and is used in an immunoassay for the quantitation of an antigen of interest (abstract). Campbell et al disclose that the use of this chemiluminescent label in assays provides a means of improving the sensitivity of measurement of proteins and polypeptides by one to two orders of magnitude (col 7, lines 27).

It would have been obvious to one of ordinary skill in the art to substitute the chemiluminescent label as taught by Campbell et al for the label of Nakanome et al because Campbell et al shows that the use of this chemiluminescent label in assays provides a means of improving the sensitivity of measurement of proteins and polypeptides by one to two orders of magnitude.

7. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanome et al and Landa et al in view of Schulz et al (Beziehungen zwischen den portalen and peripher-venosen Insulin-, proinsulin, Band 68 Heft 3, pp. 309-318 (1976).

See above for teachings of Nakanome et al and Landa et al.

Nakanome et al and Landa et al differ from the instant invention in failing to teach obtaining the sample by a probe arranged to be introduced in the Vena porta.

Schulz et al disclose obtaining a sample by insertion of a catheter (probe) in the portal vein (page 309). Obtaining a sample in this manner provides for a sample that

can be used as a diagnostic tool of pancreatic hormone secretion in man and also provides significantly enhanced portal IRI concentrations and increased PLM (proinsulin –like material).

It would have been obvious to one of ordinary skill in the art to obtain a sample as taught by Schulz et al for the modified device of Nakanome et al because Schulz et al shows that obtaining a sample in this manner provides for a sample that can be used as a diagnostic tool of pancreatic hormone secretion in man and also provides significantly enhanced portal IRI concentrations and increased PLM (proinsulin –like material)

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanome et al an Landa et al in view of Milford et al as applied to claims 1, 2, and 4 above, and further in view of Schulz et al (Beziehungen zwischen den portalen and peripher-venosen Insulin-, proinsulin, Band 68 Heft 3, pp. 309-318 (1976).

See above for teachings of Nakanome et al, Landa et al and Milford et al.

Nakanome et al, Landa et al and Milford et al differ from the instant invention in failing to teach obtaining the sample by a probe arranged to be introduced in the Vena porta.

Schulz et al disclose obtaining a sample by insertion of a catheter (probe) in the portal vein (page 309). Obtaining a sample in this manner provides for a sample that can be used as a diagnostic tool of pancreatic hormone secretion in man and also provides significantly enhanced portal IRI concentrations and increased PLM (proinsulin –like material).

It would have been obvious to one of ordinary skill in the art to obtain a sample as taught by Schulz et al for the modified device of Nakanome et al because Schulz et al shows that obtaining a sample in this manner provides for a sample that can be used as a diagnostic tool of pancreatic hormone secretion in man and also provides significantly enhanced portal IRI concentrations and increased PLM (proinsulin –like material)

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanome et al and Landa et al in view of Campbell et al as applied to claims 1, 3, 4 above, and further in view of Schulz et al (Beziehungen zwischen den portalen and peripher-venosen Insulin-, proinsulin, Band 68 Heft 3, pp. 309-318 (1976).

See above for teachings of Nakanome et al, Landa et al and Campbell et al.

Nakanome et al, Landa et al and Campbell et al differ from the instant invention in failing to teach obtaining the sample by a probe arranged to be introduced in the Vena porta.

Schulz et al disclose obtaining a sample by insertion of a catheter (probe) in the portal vein (page 309). Obtaining a sample in this manner provides for a sample that can be used as a diagnostic tool of pancreatic hormone secretion in man and also provides significantly enhanced portal IRI concentrations and increased PLM (proinsulin –like material).

It would have been obvious to one of ordinary skill in the art to obtain a sample as taught by Schulz et al for the modified device of Nakanome et al because Schulz et al shows that obtaining a sample in this manner provides for a sample that can be used as

a diagnostic tool of pancreatic hormone secretion in man and also provides significantly enhanced portal IRI concentrations and increased PLM (proinsulin –like material)

Response to Arguments

Applicant's argument (filed September 4, 2002) that Coassin et al (US 6,232,114) do not disclose or suggest a system that has both at least one reservoir and at least one photomultiplier, is found persuasive and therefore, the rejection has been withdrawn. However, these limitations are taught by the newly applied art, Nakanome et al in view of Landa et al.

See above for teachings of Nakanome et al in view of Landa et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
October 31, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/01/02